

URGENT SAFETY INFORMATION

ideFixx sterile and non-sterile microplates and screws

MRI compatibility is not validated

August 2021

Dear customers, dear users,

We have to inform you about an important safety aspect of the ideFixx microplates and screws. This does not apply to the use of the products, but rather to any subsequent diagnosis of the patient.

1. Description of the problem

In the instructions for use of the sterile and non-sterile microplates and screws, the following is explained under the point "Behavior of the products in a magnetic field (artifacts)":

The titanium implants are non-magnetic and MR-safe up to 1.5 Tesla (standard MRI devices). There is no risk from the magnetic fields that occur during an MR tomography. Stronger magnetic fields or an enlargement of the image field can nevertheless lead to significant positioning errors and artifacts. Depending on the MR pulse rate, the size of the artifact can vary considerably and possibly impair the diagnostic value of the MR image if the area in question is near the titanium implants (i.e. a few millimeters away).

There is currently no validated process that can confirm this statement. Therefore, it cannot be said with absolute certainty that the products are MRI-compatible.

2. Risks that may arise

- Heating of the implants by the magnetic field with damage to the surrounding tissue
- torsion or dislocation of the products
- Artifact formation in a size that cannot be defined

3. Affected Products

All products in the product lines:

- ideFixx sterile microplates and screws
- ideFixx non-sterile microplates and screws

4. Corrective Actions

The operating instructions have been corrected and now contain the following statement:

MRI information

The effects of the MR environment have not been determined for this product. This product has not been tested for heating or migration in the MR environment.

The correction of this error takes place in two phases:

1. New operating instructions are enclosed with products that have already been packaged before delivery. You will also receive a copy of the corrected instructions with this letter. Upon request, we can provide you with the instructions as a PDF.
2. In the case of newly produced products, the new operating instructions will be integrated into the packaging process. This contains correct statements regarding the behavior in the MRI.

Please note that this security information is not a recall. You as the user do not have to be active. The operational use of the products is not restricted by this security measure.

This safety information has already been reported to the responsible authorities.

If you have any further questions or need support, our customer service team as well as your responsible sales representative are at your disposal.

Kind regards,

